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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/412,100	10/04/1999	ZHONG-MIN WEI	21829/31-(EB	9211

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EXAMINER	
ROBINSON, HOPE A	
ART UNIT	**PAPER NUMBER**
1653	21

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 09/412,100	Applicant(s) WEI ET AL.	
	Examiner Hope A. Robinson	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7,9,30-38 and 48-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,5-7,30-38 and 48-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The request filed on January 27, 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/412,100 is acceptable and a CPA has been established. An action on the CPA follows.

2. The amendment filed on January 27, 2003 in Paper No. 15 has been received and entered. It is noted that applicant filed a petition to add two inventors and to change the name of one inventor which has been entered.

Claim Disposition

3. Claims 2-4 and 8 have been canceled. Claims 48-57 have been added. Claims 1, 5-7, 9, 30-38 and 48-57 are pending and under examination.

4. The objections to the Oath/Declaration and Information Disclosure Statement have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 5, 7 and 48-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabled for the full scope of the claim. The specification while being enabling for an isolated fragment of a hypersensitive response elicitor protein or polypeptide, said fragment having the sequence set forth in SEQ ID NO: 23 that elicits a hypersensitive response in plants, does not reasonably provide enablement for the same protein that does not elicit a hypersensitive response but has other activity in plants, said other activity comprising imparting disease resistance, enhancing plant growth, controlling insects, or a combination of these other activities. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to:

I. Quantity of Experimentation Necessary:

The claims are directed to an isolated fragment of a hypersensitive response elicitor protein or polypeptide, wherein said fragment is selected from the group consisting of a C-terminal fragment of the amino acid sequence of SEQ ID NO:23 spanning the following amino acids of SEQ ID NO: 23: 169 and 403, 210... and a fragment of the amino acid sequence of SEQ ID NO: 31 spanning amino acids 190 and 294.... of SEQ ID NO:31 and

does not elicit a hypersensitive response but has other activity in plants, said other activity comprising imparting disease resistance, enhancing plant growth, controlling insects, or a combination of these other activities. The disclosure on page 4 states that the invention is directed to isolated fragments of Erwinia hypersensitive response elicitor protein or polypeptide which fragments do not elicit a hypersensitive response in plants but are otherwise active when utilized in conjunction with plants. Laby et al. (US Patent No./PUB No. 6583107/20010011380, col. 37, claims 1-4, August 2, 2001) disclose an isolated fragment of an Erwinia hypersensitive response elicitor protein or polypeptide, wherein said fragment elicits a hypersensitive response in plants having the amino acid sequence of SEQ ID NO: 23, which encompasses the same fragment reported in the instant application as not having an hypersensitive response. Note that the Markush language of the claim 1 means that only item in the Markush listing needs to be present and Laby et al. disclose the N and C terminal fragments of the same protein having an opposing effect. Thus, the claim as written requires undue experimentation to be able to determine whether the claimed fragment does not elicit a hypersensitive response.

II. Amount of direction or guidance presented:

The specification does not disclose one reasonable method for making and using the claimed invention that bears a reasonable correlation to the entire

scope of the claim. Absent guidance/direction regarding the specific activity of the protein as the instant invention claims a that a fragment of SEQ ID NO:23 spanning 169 and 403 does not elicit a hypersensitive response and Laby et al. disclose that a fragment of SEQ ID NO:23 spanning 105 and 403 elicits a hypersensitive response which encompasses 169 and 403, the specification lacks adequate guidance/direction to enable one skilled in the art to practice the invention as claimed.

III. Presence or absence of working examples:

The specification provides examples which support a HR response (hypersensitive response), however, provides no support for no elicitation HR.

IV. Nature of the Invention:

The invention is directed to an isolated fragment of a hypersensitive response elicitor protein or polypeptide, wherein said fragment is selected from the group consisting of a C-terminal fragment of the amino acid sequence of SEQ ID NO:23 spanning the following amino acids of SEQ ID NO: 23: 169 and 403, 210... and a fragment of the amino acid sequence of SEQ ID NO: 31 spanning amino acids 190 and 294.... of SEQ ID NO:31 and does not elicit a hypersensitive response but has other activity in plants, said other activity comprising imparting disease resistance, enhancing plant growth, controlling insects, or a combination of these other activities. The scope of the patented claims encompasses the claimed invention which is

described in a Markush listing, and as the effect of the protein in the patent opposes the effect claimed in the instant application, the invention is not enabled.

V. State of the prior art and Relative skill of those in the art:

The prior art teaches the same protein fragment producing an effect that is different, completely opposite to the effect as claimed. The instant specification provides examples which support the results obtained in the prior art however, does not provide support for the claimed effect.

VI. Predictability or unpredictability of the art:

As the claimed invention is geared towards an effect that is not demonstrated or supported by the art which teaches the same protein, the invention is unpredictable.

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 30, 33 and 36 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30, 33 and 36 are indefinite as the methods recite a "applying a fragment of hypersensitive response elicitor protein or polypeptide" and the methods do not recite a step as to how the protein is being applied. Does applicant intend "applying" to mean "administering" or "treating", if so the claims should be amended to clearly recite the intended meaning.

Basis For NonStatutory Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 5, 7, 30-38 and 48-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7 and 26-43 of U.S. Patent No./PUB No. 6583107/20010011380. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to an isolated fragment of an Erwinia hypersensitive response elicitor protein or polypeptide, wherein said fragment elicits a hypersensitive response in plants. The dependent claims in the patent disclose that the protein is a fragment of SEQ ID NO:23 spanning for example, amino acid 403, 137, 105. The patented invention is also directed to a method of enhancing growth in plants comprising applying a hypersensitive response elicitor polypeptide or protein in a non-infectious form wherein said applying includes treatment and the treated seeds are planted, a method of insect control comprising applying a hypersensitive response elicitor polypeptide or protein wherein said applying includes treatment and the treated seeds are planted and a method of imparting disease resistance to plants comprising applying a hypersensitive response elicitor polypeptide or protein wherein said applying includes treatment and the treated seed are planted. The instant application is directed to an isolated fragment of an Erwinia hypersensitive response elicitor protein or polypeptide, wherein said fragment does not elicits a hypersensitive response said protein is a fragment of SEQ

ID NO:23 spanning for example, amino acid 403, 137 etc. The instant application is also directed to a method of insect control which includes treatment of the plants during the applying of the protein and planting of the treated seeds, a method of insect control which includes treatment of the plants during the applying of the protein and planting of the treated seeds and a method of imparting disease resistance which includes treatment of the plants during the applying of the protein and planting of the treated seeds and a method of imparting disease resistance which includes treatment of the plants during the applying of the protein and planting of the treated seeds. Thus, the two sets of claims are obvious variations of each other.

9. The response filed on January 27, 2003 in Paper No. 15 has been considered. Note that the rejections under 35 U.S.C. 103, Obvious Type Double Patenting and 112, second paragraph remains. It is noted that applicant filed a terminal disclaimer to obviate the Obvious Type Double Patenting rejection, however the Terminal Disclaimer is improper, because the serial number of the application or the number of the patent which forms the basis for the double patenting is missing or incorrect. Applicant is urged to submit a proper terminal disclaimer. Thus, the rejection remains.

With regard to the rejection under 35 U.S.C. 112, second paragraph the rejection remains. The response on page 7 indicates that how one applies the fragments of the present invention is readily understandable and applicant points to pages 40-41 of the specification. However, this argument is not persuasive as the limitations of the specification cannot be read into the claim. Furthermore, US Patent No./PUB No.

6583107/20010011380 which provides a similar invention has a secondary claim to clarify the term applying, see claims 27-28 of the patent.

Conclusion

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 6:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS

Patent Examiner

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